K000890

OSCAR J. SANCHEZ
Vice President
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JUN 16 2000

CHAD THERAPEUTICS, INC.
21622 Plummer Street
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CHAD
THERAPEUTICS

510(k) SUMMARY

Chad Therapeutics, Inc.

Chad Therapeutics OXYMATIC Model 401

March 17, 2000

Submitter Information:

Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Submitter's Name: Oscar J. Sanchez
Phone: (818) 882-0883

Device Name:

Proprietary name: Chad Therapeutics OXYMATIC Model 401

Common Name: Oxygen conserver

Classification Name: Non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics OXYMATIC Model 2400 and the DeVilbiss PulseDose Conserving Device, cleared for commercial distribution per K884562 and K961126, respectively.

Device Description:

The Chad Therapeutics OXYMATIC Model 401 is microprocessor-controlled device which is a combination of a low-pressure regulator and an oxygen conserver, designed for use with ambulatory oxygen systems. It delivers boluses of oxygen that are equivalent to 1 to 6 liters per minute, depending on the flow rate setting.

Intended Use:

The Chad Therapeutics, Inc. OXYMATIC Model 401 is intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Comparison of Technological Characteristics:

The Model 401 has the same technological characteristics as the predicate devices, except that the Model 401 does not have a Lack of Breathing Impulse Alarm as does the Model 2400. However, the Model 401 labeling contains a Warning about not using the device while asleep.

Summary of Testing:

Performance, mechanical, electrical, electromagnetic compatibility and environmental testing was conducted to demonstrate that the Model 401 would perform as intended.

Conclusions:

Based on the above, we concluded that the Chad Therapeutics OXYMATIC Model 401 is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Oscar J. Sanchez
Vice President, Development and Engineering
Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Re: K000890
OXYMATIC Model 401
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Sanchez:

This letter corrects our substantially equivalent letter of June 16, 2000, regarding the OXYMATIC Model 401. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSCAR J. SANCHEZ
Vice President
Development and Engineering

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Device Name:

Chad Therapeutics OXYMATIC Model 401

Indications for Use:

The Chad Therapeutics OXYMATIC Model 401 is intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

for Mark N Milhorn
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000890

PRESCRIPTION USE X -OR- OVER-THE-COUNTER USE ____